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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,384	08/20/2002	Maria Laura Gennaro	20869-2	7084
28221 7590 11/07/2008 PATENT DOCKET ADMINISTRATOR LOWENSTEIN SANDLER PC 65 LIVINGSTON AVENUE ROSELAND, NJ 07068				
EXAMINER				
SWARTZ, RODNEY P				
ART UNIT		PAPER NUMBER		
1645				
MAIL DATE		DELIVERY MODE		
11/07/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

1. Applicants' Response to Final Office Action, received 22 September 2008, is acknowledged.
2. Claims 1-8 and 11-20 are pending and under consideration.

Rejections Maintained

3. The rejection of claims 17-20 under 35 U.S.C. 112, first paragraph, scope of enablement for diagnostic methods utilizing polypeptides, is maintained for reasons of record.

Applicants argue that methods of utilizing other *M. tuberculosis* proteins were known in the art at the time of the invention and, coupled with the teachings of the instant specification concerning the strong likelihood of immunogenic properties of the claimed polypeptides, provides sufficient support for the claimed methods.

The examiner has considered applicants' arguments, in light of the teachings of the specification and the knowledge of the art, but does not find it persuasive for the reasoning put forth in the original rejection. The instant specification provides no working examples, only computer generated sequences. Thus, even if the computer generated sequences might have immunogenic properties, there remains a reasonable doubt that the computer generated sequences would be successful in diagnosis of infection with *M. tuberculosis*.

4. The rejection of claim 11 under 35 U.S.C. 102(b) as being anticipated by Horwitz et al (U.S. Pat. No. 5,108,745, 28April1992), is maintained for reasons of record.

Applicants' argue that Horowitz et al fail to teach or suggest an isolated polypeptide with an amino acid sequence selected from a group consisting of the sequences of six specific polypeptides.

The examiner has considered applicants' argument, but does not find it persuasive for the reasoning put forth in the original rejection explanation. Both the instant claim, as well as Horowitz et al, teach isolated secreted proteins from *M. tuberculosis*. In the absence of evidence to the contrary, the claimed isolated polypeptide would be one of the isolated polypeptides taught by Horowitz et al and the amino sequence would be an inherent characteristic of the polypeptide.

5. The rejection of claims 12-16 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from a rejected claim, is maintained for reasons of record.

Conclusion

6. Claims 11-20 remain finally rejected.

7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz/

Primary Examiner, Art Unit 1645

November 7, 2008